IDYLLA™ SPECIMEN REQUIREMENTS

One of the biggest challenges in oncology biomarker testing is the ability to obtain samples of sufficient size and quality. The Idylla™ System only needs a minimal amount of sample.

SOLID BIOPSY SPECIMEN REQUIREMENTS

IVD Tests		
	**MSI 510(k)[1]**	1 x 4 µm FFPE tissue section → 62.5-750 mm^2 1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥ 33%, if less, macro-dissection is required
RUO Assays		
	KRAS **NRAS-BRAF-EGFR S492R**	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥10% - if less, macro-dissection is required
	BRAF	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥50% - if less, macro-dissection is required
	EGFR	1 x 5 µm FFPE tissue section Neoplastic cells ≥10% - if less, macro-dissection is required
	**GeneFusion**	1 x 5 µm FFPE tissue section if tissue area ≥ 20 mm^2 3 x 5 µm FFPE tissue section if tissue area < 20 mm^2 Neoplastic cells ≥ 10% - if less, macro-dissection is required
	IDH1-2	Extracted DNA: 50 µl (concentration ≥ 10 ng/µl) DNA should be extracted from samples with ≥ 10% neoplastic cells - if less, an enrichment procedure is required OR FFPE: It is recommended to use maximum 3 FFPE tissue sections. Neoplastic cells ≥ 10% - if less, macro-dissection is required
	PIK3CA-AKT1	1 x 5 µm FFPE tissue section if tissue area 50-600 mm^2 1 x 10 µm FFPE tissue section if tissue area 25-300 mm^2 Neoplastic cells ≥ 20% - if less, macro-dissection is required

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LIQUID BIOPSY SPECIMEN REQUIREMENTS[2]

RUO Assays	
ctKRAS **ctNRAS-BRAF-EGFR S492R**	1 ml plasma collected using either EDTA or Streck tubes
ctEGFR	2 ml plasma collected using EDTA tubes

(1) For in vitro diagnostic use. For use on the Biocartis Idylla™ System only. The Idylla™ MSI Test, for use on the Idylla™ System, uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of seven monomorphic biomarkers (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) and subsequent melt-curve analysis. The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid. The Idylla™ MSI Test is indicated for use by healthcare professionals for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors, indicative of mismatch repair deficiency, and as an aid in the identification of probable Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome. The results from the Idylla™ MSI Test should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data. The Idylla™ MSI Test should not be used for diagnosis of CRC. The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

(2) K_2EDTA tubes: process within 4 hours. Streck Cell-free BCTs: process within 3 days.

Please refer to the product IFU for complete instructions on how to process samples on Idylla™.

Idylla™ MSI Test and Idylla™ System are cleared in the US under K211181.

Idylla™ GeneFusion Assay; Idylla™ IDH1-2 Mutation Assay Kit; and Idylla™ EGFR, KRAS, BRAF, NRAS-BRAF-EGFR S492R, PIK3CA-AKT1, ctEGFR, ctKRAS & ctNRAS-BRAF-EGFR S492R Mutation Assays are for Research Use Only; not for use in diagnostic procedures.

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